REMARKS

Claims 16-18 and 28-30 are currently under examination and have been rejected. New claims 60-66 have been added.

Priority Claim

The specification has been amended to recite a priority claim to the parent PCT application under 35 U.S.C. 371. Because this priority claim was acknowledged on the Filing Receipt for the present application, no separate Petition is required in amending the application to recite it.

Specification

Applicants have corrected several typographical and/or spelling errors that appeared in the specification. Thus, no new matter has been added.

Claim Rejection Based on 35 U.S.C. 112

Claims 16-18 and 28-30 were rejected under 35 U.S.C. 112, first paragraph, for failing to meet the written description requirement.

The ground of rejection alleges that the application provides no examples of polynucleotide sequences that vary from SEQ ID NO: 1 yet are related to cancerous status of the cell. In response, Applicants have amended claims 16 and 28 to recite SEQ ID NO: 1 alone and have canceled claims 18 and 30 (which had been limited to only that sequence). Thus, this ground of rejection is overcome.

Claims 16-18 were rejected under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement. The rejection contends that the specification does not provide clear indication that an increase in SEQ ID NO: 1 expression is indicative of a particular cancerous status of a cell.

In response, Applicants have amended claim 16 to recite use of SEQ ID NO: 1 and have canceled claim 18. Applicants respectfully traverse this ground of rejection and urge that the data of Example 2 provide such a correlation for breast tumor. Applicants have added new claim 63 drawn to a breast cell. The data of Table 3 (at page 39) show clear correlation between the cancerous state and the increased copy number (i.e., increased expression) of TRIP13 (a gene comprising the sequence of SEQ ID NO: 1). This gene expression was elevated in cancerous cells although not in all of the samples. Thus, if the gene shows increased expression then the cell is cancerous (e.g., Table 3 does not show increased expression in normal cells). Since claim 16 is drawn to detecting elevated expression it is thereby also drawn to detecting cancer (or cancerous status of the cells of the sample). Consequently, claim 16 is enabled.

Claims 28-30 were rejected under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement.

In response, Applicants have amended claim 28 to recite detecting cancer using the polynucleotide of SEQ ID NO: 1 and have canceled claim 30. Applicants above remarks regarding claim 16 are believed to be equally applicable to claim 28. Thus, the data of Table 3 (page 39 of the application) show that elevated TRIP13 was present in cancerous samples and correlated with the presence of cancer (also see the other disclosure on page 39).

62, which track previous claims 28-30 and are therefore supported in the specification. Applicants respectfully urge that this ground of rejection does not apply to new claims 60-62.

Claims 16-18 and 28-30 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claims 16-18 and 28-30 were deemed indefinite for use of the terms "elevated expression" in claim 16 or "an increase in expression" in claim 28. The Examiner acknowledges that the application provides guidance on comparing with normal or non-cancerous cells at pages 23 and 31 (see Office Action at page 14, lines 7-10).

In response, Applicant has amended claims 16 and 28 to recite that increased or elevated expression means increased copy number and/or increased mRNA levels relative to normal (i.e., non-cancerous cells and samples). This is clearly supported in the application on the pages mentioned by the Examiner (such as at page 23, lines 29-32, for measuring steady state mRNA levels and at page 6, lines 4-6, and page 31, lines 28-29, for expression in cancer cells/tissues versus normal cells/tissues) as well as at page 23, lines 12-21, for measurement of mRNA production and at page 2, line 28, over to page 3, line 3, disclosing that both gene amplification and increased mRNA represent forms of increased expression important in using the methods of the invention and that the gene of the invention (TRIP13 is both amplified and over-expressed in cancerous but not in normal cells). Thus, Applicants believe that the amendments to claims 16 and 28 are adequately supported in the application as filed and thus these amendments add no new matter.

Claim 16 was rejected as indefinite for reciting "cancerous status of a cell." In response, Applicants respectfully urge that the meaning of this phrase is clear from the application as filed. For example, at page 11, lines 18-20, it is stated that, "[g]ene

sequences that demonstrate amplification and/or over-expression are indicative of the **cancerous status of a given cell**." (emphasis added) Applicants also teach that TRIP13 (e.g., SEQ ID NO: 1) is such a gene when cancerous versus normal tissues are compared (application at page 11, lines 20-26). Thus, "cancerous status" means the cell is cancerous so that the elevated expression indicates "the cancerous status" of the cell. This phrase can have no other meaning because "cancerous status" is indicated by the elevated expression of the genes of the application, which occurs only in tumor (i.e., cancerous) cells and not in normal cells (see, for example, page 2, line 32, over to page 3, line 3).

In an effort to advance prosecution, Applicants have amended claim 16 to recite a "method for identifying a cancerous cell" and this is adequately supported by the above remarks regarding "cancerous status" so that no new matter has been added.

Claim 28 was rejected as indefinite because it lacks a final step that connects to the preamble. In response Applicants have amended claim 28 to recite that the increased expression indicates cancer.

In view of the above amendments and remarks, Applicants believe that this ground of rejection has been overcome and respectfully request that this ground of rejection be withdrawn.

Claim Rejection Based on 35 U.S.C. 102

Claims 28-29 were rejected under 35 U.S.C. 102 as being anticipated by Dai et al (US 2003/0224374, filed 14 June 2002), which teaches a method of detecting cancer in a sample from a patient showing an increase in expression of a gene that encodes the amino acid sequence of Applicants' SEQ ID NO: 7. The reference does not disclose

SEQ ID NO: 1 *per se*. In response, Applicants have amended claim 28 to recite use of SEQ ID NO: 1.

Claims 28-29 were rejected under 35 U.S.C. 102 as being anticipated by Mutter et al (US 6,703,204, filed 27 July 2001), which teaches a method of detecting cancer in a sample from a patient showing an increase in expression of a gene that encodes the amino acid sequence of Applicants' SEQ ID NO: 7. The reference does not disclose SEQ ID NO: 1 *per se*. In response, Applicants have amended claim 28 to recite use of SEQ ID NO: 1.

In addition, Applicants respectfully urge that new claims 60-62 are free of this art because, while one of the cited references discloses use of a sequence for monitoring progress of tumor development (see Mutter et al (Abstract)), neither reference appears to disclose a method for detecting progress toward developing cancer.

Applicants request that the Commissioner charge any additional fee for this correspondence, or credit any overpayment, to Deposit Acct. No. 03-0678.

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Respectfully submitted,

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